

**Amendment and Response**

Applicant: Cynthia T. Clague et al.

Serial No.: 10/694,037

Filed: October 27, 2003

Docket No.: M190.242.101/P-11210.00

Title: METHOD AND APPARATUS FOR MAKING PRECISE INCISIONS IN BODY VESSELS

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**REMARKS**

The following remarks are made in response to the Office Action mailed on June 5, 2007. Claims 1-6, 15-23 and 32-34 are pending. Claims 7-14, 24-31 and 35-46 have been withdrawn from consideration. Claims 1-6, 15-23 and 32-34 were rejected. With this Response, claims 1 and 18 have been amended. Claims 1-6, 15-23 and 32-34 remain pending in the application and are presented for reconsideration and allowance.

**Claim Rejections under 35 U.S.C. § 102**

Claims 1-3 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro US Patent No. 5,314,440. Of these claims, claims 1 and 18 are the two pending independent claims in the application. Claim 2-3 depend from independent claim 1, and claims 19-20 depend from independent claim 18. With this response, claims 1 and 18 are amended, and the dependent claims are unchanged.

Amended claims 1 and 18 include features on not shown or made obvious in the prior art of record. Claim 1 has been amended to include the features where “the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side.” Also, claim 18 has been amended to include the features where “the first cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending first cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side.”

These features are not shown or made obvious in Shapiro. For example, Shapiro does not show the claimed features of “the . . . cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending . . . cutting blade.” Rather, Shapiro shows that “the cutting edge 72 is formed at an angle between 30 degrees and 40 degrees to the plane of the shaft 60.” (See column 4, lines 54-56 and Figure 7 of Shapiro.) The angled cutting edge is

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consistent throughout the specification, and nowhere does Shapiro show or make obvious the claimed features.

Also, Shapiro does not show the claimed features where “the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side.” Rather, Shapiro shows where the cutting member is “formed with a hook shaped contour terminating in a cutting blade.” (See column 4, lines 46-49 and Figure 7.)

These distinctions highlight that the device of Shapiro as configured is not suited for the same purposes as the “vessel wall cutting instrument” set forth in the claims. With the amended features, the cutting blade is able to pierce the vessel wall with the cutting tip and then the major portion of the cutting blade is able to slide within the lumen without necessarily affecting the size of the piercing. This aspect is not possible with the hook shaped contour. In Shapiro, after the lumen is pierced, the size of the piercing increases as the cutting blade slides into the lumen. As discussed in the background of the present application, a consistent precise slit length is difficult to achieve with a “curved” back of the blade. The cutting edge 72 of Shapiro needs to be positioned within the lumen at an angle to its lateral direction so that the cutting edge is against the inside of the vessel wall for cutting. Cutting in this position is made difficult because the hooked shaped contour must be manipulated within the lumen to achieve this position, which has a tendency to cut or move the blade away from a precise location and achieve a consistent slit.

Further, the hooked back of the blade when used to piece vessel walls is used as a blade stop to limit downward movement of the shaft axis so as not to extend into the opposite side of the vessel wall. This aspect is set forth in the prior and particularly in U.S. Patent No. 5,776, 154 at column 5, lines 8-10, which patent is discussed in the background of the present application. The features of the present claims allow the cutting tip to penetrate the vessel along the direction of the lumen so that the likelihood of piercing opposite vessel wall is reduced in a manner that does not cause the piercing to open up much wider than when initially pierced, unlike in Shapiro.

The prior art does not make obvious a modification to Shapiro to meet the claimed features because Shapiro is designed as a scissors type device to cut through the external sides of a portion of the patient during surgery. The hook end also adds strength and thus versatility to

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the blade when performing these cuts on a number of portions of the patient. On the other hand, there is no recognition in the prior art of how to form a blade for precisely piercing a vessel wall so that the piercing does not grow in size dependent on how far the length of the major portion of the blade is inserted. Simply put, the hook portion of Shapiro is not suited for piercing and cutting the vessel wall from the lumen side in a manner that is consistent and precise. The hook portion of Shapiro is suited for cutting through vessel from the exterior of the vessel wall on opposite sides of the vessel.

Based on the above, Applicants submit that the prior art does not show or make obvious the amended features of claims 1 and 18. By virtue of their dependency, claims 2-3 and claims 19-20 are also patentably distinguishable from the prior art. Accordingly, Applicants respectfully request removal of the rejection and allowance of claims 1-3 and 18-20.

**Claim Rejections under 35 U.S.C. § 103**

Claims 4-6, 15-17, 21-23 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,036,641. The rejected claims are not amended. Claims 4-6 and 15-17 depend from independent claim 1, and claims 21-23 and 32-34 depend from independent claim 18. As discussed above, independent claims 1 and 18 have been amended and the dependent claims thus include the amended features of the independent claims.

Independent claims 1 and 18 have been amended to be patentably distinguishable from Shapiro. Taylor also does not teach the amended features of the independent claims. Taylor instead is directed toward an instrument for stabilizing a beating heart during artery bypass surgery. The disclosure relates to a stabilizing device that exerts a stabilizing force when in contact with the beating heart. There is no discussion related to particular instruments for cutting a vessel wall that are related to the amended independent claims.

Because the amended features of the independent claims 1 and 18 are missing from each of Shapiro and Taylor individually, these features would be missing from any proposed combination of Shapiro and Taylor. Again, by virtue of their dependency, claims 4-6, 15-17, 21-

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23, and 32-34 are patentably distinguishable from the combination of Shapiro and Taylor.

Accordingly, Applicants respectfully request removal of the rejection and allowance of claims 4-6, 15-17, 21-23, and 32-34.

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**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 1-6, 15-23 and 32-34 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-6, 15-24 and 32 are respectfully requested.

Applicants hereby authorize the Commissioner for Patents to charge Deposit Account No. 50-0471 in the amount of \$460 to cover the fees as set forth under 37 C.F.R. 1.16(h)(i).

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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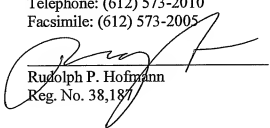
Respectfully submitted,

Cynthia T. Clague et al.,

By their attorneys,

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